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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,144	10/17/2006	Ichirou Shimomura	64656 (46590)	9423

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BOSTON, MA 02205

EXAMINER
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LEE, JAE W

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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06/15/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/561,144

**Applicant(s)**

SHIMOMURA ET AL.

**Examiner**

Jae W. Lee, Ph.D.

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/12/2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15, 18-28, 31-38, 41, 42 and 45-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15, 18-28, 31-38, 41, 42 and 45-51 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Application status***

Claims 1-15, 18-28, 31-38, 41, 42 and 45-51 are pending in the instant application.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 10, 12, 33 and 34, drawn to a protein comprising the same or substantially the same amino acid sequence as the amino acid sequence starting at Amino Acid No. 1 in the amino acid sequence shown by SEQ ID NO:2 or 4 or a salt thereof.

Group II, claim(s) 4-8, 11, 12, 18, 21, 23-26, 37 and 38, drawn to a nucleic acid comprising a base sequence encoding the protein of claim 1.

Group III, claim(s) 14, 15, 27, 28, 41 and 42, drawn to a prophylactic/therapeutic method for a disease involved in differentiation of skeletal muscle cell and/or metabolic abnormality, which comprises administering an effective amount of the protein of claim 1, the partial peptide of claim 3 or a salt thereof, or the nucleic acid of claim 4, to a mammal.

Group IV, claim(s) 19, 20, 21, 22, 25, 26, 49, 50 and 51, drawn to an antibody against the protein of claim 1 or the partial peptide of claim 3 or a salt thereof.

Group V, claim(s) 31 and 32, drawn to a screening method for a prophylactic/therapeutic substance for a disease involved in differentiation of skeletal

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muscle cell and/or metabolic abnormality, which comprises using the protein of claim 1 or the partial peptide of claim 3 or a salt thereof.

Group VI, claim(s) 35 and 36, drawn to a screening method for a prophylactic/therapeutic substance for a disease involved in differentiation of skeletal muscle cell and/or metabolic abnormality, which comprises using the nucleic acid of claim 4.

Group VII, claim(s) 45-48, drawn to a screening method for a prophylactic/therapeutic substance for a disease involved in differentiation of skeletal muscle cell and/or metabolic abnormality, which comprises using the antibody of claim 19.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Jacobs et al. (WO/2000/21990) teach a nucleic acid sequence that is 100% homologous to Applicants SEQ ID NO: 1 from nucleotide base 1-309 (please see sequence alignment results attached), which corresponds to the limitation of claim 6, in the recitation of "[a] nucleic acid comprising a base sequence encoding a polypeptide comprising the same or substantially the same amino acid sequence as the amino acid sequence shown by SEQ ID NO:2 or 4, or a portion thereof," and thus, the shared technical feature of the groups is not a "special technical feature", unity of invention

between the groups does not exist.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are unrelated and distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Group is not required for another thereby presenting a search burden on the Examiner, restriction for examination purposes as indicated is proper.

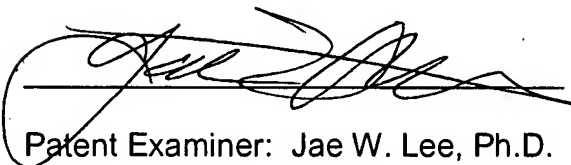
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Patent Examiner: Jae W. Lee, Ph.D.



RICHARD HUTSON, PH.D.  
PRIMARY EXAMINER